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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/570,589

06/12/2007

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64995(70904)

5282

21874 7590 08/15/2011
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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

08/15/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,589	Applicant(s) KONDO, KAZUHIRO
	Examiner MARIA MARVICH	Art Unit 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 14-16 and 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/28/06, 7/10/06, 11/29/06,1/3/07 .

DETAILED ACTION

This office action is in response to an amendment filed 7/25/11. Claims 1-26 are pending.

The amendment filed 2/28/06 was improper as filed. To be proper the amendment to the specification should replace paragraphs and not sentences within the document. However, in the interest of compact prosecution, the amendment has been accepted.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-3, 7-13 and 17) in the reply filed on 7/25/11 is acknowledged. Claims 4-6, 14-16 and 18-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/25/11.

Information Disclosure Statement

An information disclosure statement filed 2/28/06 has been identified and the documents considered. The corresponding signed and initialed PTO Form 1449 has been mailed with this action. A document under Foreign Patent Documents and a document filed under NPL have not been considered and have been crossed out as these publications are not in English nor are they accompanied by an explanation of the relevance, "as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, unless a complete translation is provided (See MPEP § 609.05).

An IDS filed 11/29/06 was not accompanied by the documents, however this IDS is the same as the IDS filed 7/10/06, which contained the missing documents. The corresponding signed and initialed PTO Form 1449 has been mailed with this action. In the IDS filed 1/3/07, the documents listed as a Search Report *has been considered* but has been crossed off the 1449 so that it will not appear on the face of any patent issuing from the instant application. These submissions do not constitute documents under 37 CFR 1.98. The corresponding signed and initialed PTO Form 1449 has been mailed with this action.

Claim Objections

Claims 1-3, 7-13 and 17 are objected to because of the following informalities: In claim 1 and 11, the vector is said to “originate” in HHV-6. The phrase “as represented by SEQ ID NO:” throughout the claims creates a broad breadth of encompassed scope. Both of these issues are addressed below in the 112 first rejection. However, note is made here as it does not appear as if the claims are intended to be so interpreted. If so, it would be preferable to amend Claim 1 to --A recombinant HHV-6 viral vector--. As well, the language “represented by” should be amended to --is the sequence of SEQ ID NO:--.

When referring to previous limitations, it is proper to use the article “the” as opposed to “a”. In each of claims 2, 3, 7-10, 12, 13 and 17 should be amended to recite --The-- as opposed to “A”. In claim 2, line 3 and claim 12, line 4, “a HHV-6” should be --the HHV-6--.

In claim 3, for accuracy, the virus --which is an H6R28 virus or an H6R24 virus--. Also note that articles are required prior to each virus.

In claim 7, “or” has been deleted but “4” has not.

As well, it is not clear how an RNA molecule can be positioned in the vector. The RNA can be encoded by the vector. However, mixing DNA and RNA is not typically easily accomplished.

In claim 8, articles are required prior to each of the “substances”. It is also noted that “kind of substance” is not the best vernacular to be used in the claim. It is recommended that the term be amended to --biomolecule—or --molecule--.

Claim 9 does not further limit claim 7. That the vector is used for gene therapy does not add any structural limitations. As the claims are composition claims, functional language is improper unless it is also accompanied by the structural property responsible.

In claims 11-13 and 17, a “producing method” Should be amended to --A method of producing-- and --The method of producing-- in the dependent claims.

Claim 17 recites that the exogenous nucleotide sequence is inserted in side a normal cell and/or an umbilical cord blood cell”. It is not clear if this means the method of producing is in said cells or if in addition to the insertion into the viral vector the exogenous nucleotide sequence is also inserted into the cell. The claim requires clarification as to which. In the case of the later, it would be proper to recite --is additionally inserted into the cell--. However, it is not clear why one would do so.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because claim 3 refers to biological deposits and to satisfy the “how to make” requirement must specify the details of the cell line such that one of skill in the art can produce the recited cells.

More particularly, claim 3 is drawn to or encompasses use of a virus H6R28 and H6R24. As such, this application discloses molecules that are encompassed by the definitions for biological material set forth in 37 C.F.R. 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

It is unclear that the virus of claim 3 will be readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Therefore, in order for a deposit to meet all criteria set forth in 37 C.F.R. 1.801 through 1.809, Applicant or Assignee must provide assurance of compliance with provisions of 37 C.F.R. 1.801-1.809 in the form of a declaration or Applicant’s representative must provide a statement. The content of such a declaration or statement is suggested by the encoded attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, Applicant is required to submit a verified statement from a person in a position to corroborate the statement that the biological material which had been deposited is the biological material specifically identified in the applicants as filed (37 C.F.R. 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the

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specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

Specification

The specification is objected to as the reference to the deposit in the specification does not indicate that the material will be irrevocably available. The MPEP teaches “The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).” (see MPEP 2404.01).

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 7-13 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant HHV-6 viral vector the comprises an exogenous nucleotide sequence into a HHV-6 region selected from the group consisting of U2-

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U8 and U24-U5 and a method of producing therein wherein the method comprises inserting the exogenous nucleotides into the region(s), does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

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The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a recombinant viral vector that originates in HHV-6. The vector comprises an exogenous nucleotide sequence inserted into a portion corresponding to at least one region from U2-U8, U24 and U25. Claim 11 is drawn to a method of making the virus. Dependent claims 2 and 12 limit the insertion site to between nucleotides 9041-17446 or 36250-37775. The scope of the invention is extremely broad in the virus is *any* virus so long as it originates in HHV-6. As this is a composition, and the language is so broad, the resulting virus that only originates in HHV-6 encompasses a number of viruses that have any number of sequences in common with HHV-6. The relationship between starting material and ending vector is not clear and in the absence of structural requirements is extremely broad. The scope is not improved by recitation that the nucleotides are represented by the SEQ ID NO:s. .

Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/ functional characteristics of antagonists, the lack of adequate working examples and the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.” In this case, the claims are directed towards any virus that originates in HHV-6 with an insertion into a

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corresponding number of regions. However, the breadth of enablement is not commensurate in scope with the claims. The amount of direction presented and the number of working examples provided in the specification were very narrow compared to the wide breadth of the claims at issue

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al (abstract, 28th International Herpesvirus Workshop, July 26-31, 2003, 8.31).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. A translation of PCT/JP03/04553 is also required to ascertain that the designation that this application is a continuation of JP 2002-108550

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Kondo et al teach a recombinant HHV-6 viral vector comprising an exogenous nucleic acid encoding an enzyme as well as marker that is situated in the region between nucleotides 9041-17446 of SEQ ID NO:1.

Claims 1-3, 7-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al (US 20080226677; see entire document).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. A translation of PCT/JP03/04553 is also required to ascertain that the designation that this application is a continuation of JP 2002-108550

Mori et al teach a recombinant HHV-6 viral vector comprising an exogenous nucleic acid encoding BAC and marker that is situated in the region between nucleotides 9041-17446 of SEQ ID NO:1 (see e.g. para 0018-0030).

Claims 1-3, 7, 9-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hippenmeyer et al (US 5,972,666; see entire document).

Hippenmeyer et al teach a recombinant HHV-6 vector comprising a deleted U25-U27 region which encompasses regions between 36250-37775 and U25 wherein sequences are inserted into the deleted region such as vaccine sequences (see figure 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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